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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,874	06/07/2005	Yasser H Alsafadi	US020572US	8499
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EXAMINER				
PAULS, JOHN A				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/537,874

Applicant(s)

ALSAFADI ET AL.

Examiner

JOHN A. PAULS

Art Unit

4114

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 June 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/ISD)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date 7 June 2005

DETAILED ACTION

Status of Claims

1. This action is in reply to the application filed on 7 June, 2005
2. Claims 1 - 20 are currently pending and have been examined.

Information Disclosure Statement

3. The Information Disclosure Statement filed on 7 June, 2005 has been considered. An initialed copy of the Form 1449 is enclosed herewith.

Drawings

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p) (5) because they do not include the following reference sign(s) mentioned in the description: 10, 12, 14, 16, 18, 20, 22, 24, 26 and 28 relative to Figure 1. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the

applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

5. The disclosure is objected to because of the following informalities: use of the acronym "DCMR". Appropriate correction is required.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1 – 12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The steps recited do not qualify as a statutory process. In order for a method to be considered a "process" under §101, a claimed process must either: (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials). Diamond v. Diehr, 450 U.S. 175, 184 (1981); Parker v. Flook, 437 U.S. 584, 588 n.9 (1978); Gottschalk v. Benson, 409 U.S. 63, 70 (1972). If neither of these requirements is met by the claim, the method is not a patent eligible process under §101 and is non-statutory subject matter. Although the steps are performed using a computer, the computer is a field of use

limitation because the steps are human actions that do not require (i.e. are not tied to) the computer.

8. **Examiner's Note:** The Examiner has pointed out particular references contained in the prior art of record within the body of this action for the convenience of the Applicant. Although the specified citations are representative of the teachings in the art and are applied to the specific limitations within the individual claim, other passages and figures may apply. Applicant, in preparing the response, should consider fully the entire reference as potentially teaching all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the Examiner.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
11. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazess et al. (US 6,160,866 A) and in further view of Barry et al. (US 6,081,786 A).

CLAIMS 1 and 2

Mazess as shown discloses the following limitations:

- *determining at least one physical characteristic of the patient from the examination; (see at least Mazess column 5 line 29 – 32; column 9 line 7 – 9 and column 21 line 54 - 56);*
- *obtaining established norms for the at least one characteristic; (see at least Mazess column 21 line 58 – 65 and column 23 line 59 – 65);*
- *selecting one of the established norms to be applied to the patient based on the determination of the at least one characteristic, the guidelines relating to the determination of the at least one characteristic and the information about the patient other than from the examination; (see at least Mazess column 31 line 17 – 34);*
- *applying the norm to the anatomical feature to obtain a normal value for a measurable anatomical feature or a range of normal values for a measurable anatomical feature and comparing the determined anatomical feature of the*

patient to the normal value or range of normal values to. determine whether the determined anatomical feature is indicative of normalcy of the patient or abnormalcy of the patient; (see at least Mazess column 15 line 46 – 66).

Mazess shows the limitations above. Mazess does not specifically disclose the following limitations, however, Barry does:

- *obtaining guidelines relating to the determination of the at least one characteristic from the examination; (see at least Barry column 5 line 7 – 20 and Figure 2 and 3);*
- *obtaining information about the patient other than from the examination; (see at least Barry column 4 line 56 to column 5 line 6).*

Barry discloses a system and method for selecting a treatment regimen by applying patient information to an inference engine and a knowledge base. It would be obvious to one of ordinary skill in the art at the time of the invention to modify the measurement system of Mazess with the treatment selection system of Barry because obtaining guidelines and historical patient information for use in an inference engine allows complex treatment options to be made available. (see Barry column 1 line 29 – 39).

Examiner notes that it would be an obvious modification to Barry to have the system respond with a fetal development stage.

12. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mazess et al. (US 6,160,866 A) and in further view of Barry et al. (US 6,081,786 A) and in further view of **Official Notice**.

CLAIM 3

The combination of Mazess/Barry as shown discloses the limitations above. Mazess/Barry does not specifically disclose the following limitations:

- *applying the norm to the ratio to obtain a normal value for the ratio or a range of normal values for the ratio and comparing a ratio derived from the determined anatomical features of the patient to the derived normal value or range or range of normal values to determine whether the at least one anatomical feature falls is indicative of normalcy of the patient or abnormalcy of the patient.*

Mazess discloses averaging values, values that are a pre-defined amount from a statistical norm, area values and other mathematical manipulations of measured data. The combination of Mazess/Barry does not specifically disclose a ratio. However, Examiner takes **Official Notice** that calculating a ratio of to measured values is old and well known in the arts, therefore it would be obvious to one of ordinary skill in the arts at the time of the invention to modify Mazess/Barry with the **Official Notice** taken so that a ratio between to measured values is calculated because it is a convenient measure of deviation from a normal value.

13. Claims 4 - 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazess et al. (US 6,160,866) and in further view of Barry et al. (US 6,081,786 A) and in further view of Laros (US 5,928,168 A).

CLAIM 4

The combination of Mazess/Barry as shown discloses the limitations above. Mazess/Barry does not specifically disclose the following limitations, however, Laros does:

- *the step of performing the examination comprises the step of performing an ultrasound examination of the patient; (see at least Laros column 2 line 8 – 20).*

Laros discloses an apparatus and method for estimating fetal development using ultrasound technology. It would be obvious to one of ordinary skill in the art at the time of the invention to modify the measurement system of Mazess/Barry with the ultrasound technology of Laros because using ultrasound technology would expose the patient and fetus to more benign radiation.

CLAIM 5

The combination of Mazess/Barry/Laros as shown discloses the limitations above. Additionally, Mazess discloses the following limitations:

- *measuring a length, size or diameter of a bone in the patient or measuring a circumference of a head or abdomen; (see at least Mazess column 21 line 54 – 56).*

14. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mazess et al. (US 6,160,866) and in further view of Barry et al. (US 6,081,786 A) and in further view of Laros (US 5,928,168 A) and in further view of **Official Notice**.

CLAIM 6

The combination of Mazess/Barry/Laros as shown discloses the limitations above.

Mazess also discloses the following limitations:

- *measuring at least two anatomical features; (see at least Mazess column 23 line 41 – 65 and column 24 line 11 - 19).*
- *calculating a ratio of two anatomical features, guidelines relating to the ratio of the two anatomical features being obtained; (see at least Mazess column 23 line 59 – 65).*

Mazess/Barry/Laros does not specifically disclose calculating a ratio per se, however, Mazess discloses averaging values (see at least Mazess column 23 line 59 – 65), values that are a pre-defined amount from a statistical norm (see at least Mazess column 18 line 1 - 3), area values (see at least Mazess column 19 line 36 – 40) and other mathematical manipulations of measured data (see at least Mazess column 9 line 7 – 12). Mazess/Barry/Laros does not specifically disclose a ratio. However, Examiner takes **Official Notice** that calculating a ratio of to measured values is old and well known in the arts, therefore it would be obvious to one of ordinary skill in the arts at the time of the invention to modify Mazess/Barry/Laros with the **Official Notice** taken so that a ratio between to measured values is calculated because it is a convenient measure of deviation from a normal value.

15. Claims 7 - 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazess et al. (US 6,160,866) and in further view of Barry et al. (US 6,081,786 A) and in further view of Wong et al. (US 6,260,021 B1).

CLAIMS 7 - 9

The combination of Mazess/Barry as shown discloses the limitations above. Mazess/Barry does not specifically disclose the following limitations, however, Wong does:

- *expressing the determination of the at least one characteristic in XML syntax; (see at least Wong column 2 line 21 – 30 and 38 – 45; column 12 line 6 – 13 and column 13 line 34 – 37);*
- *expressing the established normal ranges of the at least one characteristic in XML syntax; (see at least Wong column 2 line 21 – 30 and 38 – 45; column 12 line 6 – 13 and column 13 line 34 – 37);*
- *the information about the patient other than obtained from the results of the examination is obtained from a hospital or departmental information system using HL7 messaging which uses XML syntax; (see at least Wong column 2 line 21 – 30 and 38 – 45; column 7 line 59 – 62; column 12 line 6 – 13 and column 13 line 34 – 37).*

Wong discloses an apparatus and method for distributing medical images over a computer network using XML and HL7 formats. It would be obvious to one of ordinary skill in the art at the time of the invention to modify the measurement system of Mazess/Barry with the image and other medical information formats of Wong because using these standards enables uniform access and ready distribution of medical images and associated records in electronic form (see Wong column 1 line 7 – 10).

16. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mazess et al. (US 6,160,866) and in further view of Barry et al. (US 6,081,786 A) and in further view of Wong et al. (US 6,260,021 B1) and in further view of

Official Notice.

CLAIM 10

The combination of Mazess/Barry/Wong as shown discloses the limitations above.

Mazess/Barry/Wong does not disclose the following limitations:

- *the information about the patient is coded in the hospital or departmental information system, further comprising accessing a vocabulary to decode the information about the patient prior to the selection of one of the established norms.*

However, Examiner takes **Official Notice** that it is old and well known in the arts to use coding to indicate information about a patient, in particular as it regards diagnosis information. Therefore it would be obvious to one of ordinary skill in the art at the time of the invention to modify the measurement system of Mazess/Barry/Wong with the **Official Notice** taken so that patient data was coded and that information to decode the information would also be accessible.

17. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mazess et al. (US 6,160,866) and in further view of Barry et al. (US 6,081,786 A) and in further view of Sasmor et al. (US 4,825,869).

CLAIM 11

The combination of Mazess/Barry as shown discloses the limitations above. Mazess/Barry does not specifically disclose the following limitations, however, Sasmor does:

- *the selection of one of the established norms is performed by an inference engine;* (see at least Sasmor column 17 line 1 – 12 and Figure 17).

Sasmor discloses an apparatus and method for automatically performing a clinical assessment using a knowledge base and inference engine. It would be obvious to one of ordinary skill in the art at the time of the invention to modify the measurement system of Mazess/Barry with the knowledge base and inference engine of Sasmor because using an inference engine in combination with an expert knowledge base allows a comprehensive analysis of the patient's condition. (see Sasmor column 2 line 12 – 23).

18. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mazess et al. (US 6,160,866 A) and in further view of Wong et al. (US 6,260,021 B1) and in further view of Barry et al. (US 6,081,786 A).

CLAIM 12

Mazess as shown discloses the limitations above. Mazess does not specifically disclose the following limitations:

- *determining at least one physical characteristic of the patient from the examination;* (see at least Mazess column 5 line 29 – 32; column 9 line 7 – 9 and column 21 line 54 - 56);
- *obtaining established norms for the at least one characteristic;* (see at least Mazess column 23 line 59 – 65);
- *obtaining information about the patient other than from the examination from a hospital or departmental information system using HL7 messaging which uses XML syntax;* (see at least Mazess column 30 line 61 – 65).

Mazess does not specifically disclose information in the HL7 or XML format; however, Wong discloses an apparatus and method for distributing medical images over a computer network using XML and HL7 formats with the following limitations:

- *expressing the determination of the at least one characteristic in XML syntax;* (see at least Wong column 2 line 21 – 30 and 38 – 45; column 12 line 6 – 13 and column 13 line 34 – 37);

- *expressing the established normal ranges of the at least one characteristic in XML syntax; (see at least Wong column 2 line 21 – 30 and 38 – 45; column 12 line 6 – 13 and column 13 line 34 – 37);*
- *obtaining information using HL7 messaging which uses XML syntax; (see at least Wong column 2 line 21 – 30 and 38 – 45; column 7 line 59 – 62; column 12 line 6 – 13 and column 13 line 34 – 37).*

It would be obvious to one of ordinary skill in the art at the time of the invention to modify the measurement system of Mazess with the image formats of Wong because using these standards enables uniform access and ready distribution of medical images and associated records in electronic form (see Wong column 1 line 7 – 10).

The combination of Mazess/Wong discloses the limitations shown above.

Mazess/Wong does not disclose the following limitation, however, Barry does:

- *obtaining guidelines relating to the determination of the at least one characteristic from the examination, the guidelines being described using a methods ontology based on semantic web technology; (see at least Barry column 5 line 7 – 20 and Figure 2 and 3);*
- *providing an inference engine to receive the determination of the at least one characteristic, the guidelines relating to the determination of the at least one characteristic and the information about the patient other than from the examination and selecting one of the established norms to be applied to the*

patient based thereon; (see at least Barry column 4 line 56 to column 5 line 20 and Table 2).

Barry discloses a system and method for selecting a treatment regimen by applying patient information to an inference engine and a knowledge base. It would be obvious to one of ordinary skill in the art at the time of the invention to modify the measurement system of Mazess/Wong with the treatment selection system of Barry because using an inference engine to make decisions based on medical information allows complex treatment options to be made available. (see Barry column 1 line 29 – 39).

Examiner notes that it would be an obvious modification to Barry to have the system respond with a fetal development stage.

19. Claim 13, 14, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazess et al. (US 6,160,866 A) and in further view Barry et al. (US 6,081,786 A).

CLAIM 13 and 14

Mazess as shown discloses the following limitations:

- *a modality for obtaining physical measurements of a patient and enabling at least physical characteristic of the patient to be derived; (see at least Mazess column 5 line 29 – 32; column 9 line 7 – 9 and column 21 line 54 - 56);*

- *a processor coupled to said modality; a repository of medical information about the patient coupled to said processor; (see at least Mazess column 6 line 28 – 38 and column 7 line 3 - 12);*
- *at least one library of norms relating to characteristics of the patient coupled to said processor; (see at least Mazess column 21 line 58 – 65 and column 23 line 59 – 65).*

Mazess discloses the limitations shown above. Mazess does not disclose the following limitation, however, Barry does:

- *at least one library coupled to said processor and containing clinical guidelines associated with a procedure used by said modality to derive the characteristics; (see at least Barry column 5 line 7 – 20 and Figure 2 and 3);*
- *said processor being arranged to receive the characteristics of the patient derived by said modality, medical information about the patient from said repository of medical information, the norms from said at least one library of norms and the clinical guidelines from said at least one library of clinical guidelines and select one of said norms which is most appropriate for use with the patient; (see at least Barry column 4 line 56 to column 5 line 20 and Table 2);*
- *links between said processor, said repository of medical information, said at least one library of norms and said at least one library of clinical guidelines are Internet or Intranet connections; (see at least Barry column 8 line 50 - 61 and Figures 2 and 3).*

Barry discloses a system and method for selecting a treatment regimen by applying patient information to an inference engine and a knowledge base. It would be obvious to one of ordinary skill in the art at the time of the invention to modify the measurement system of Mazess/Wong with the treatment selection system of Barry because using an inference engine to make decisions based on medical information allows complex treatment options to be made available. (see Barry column 1 line 29 – 39).

Examiner notes that it would be an obvious modification to Barry to have the system respond with a fetal development stage.

CLAIMS 19 and 20

Mazess discloses the limitations shown above. Mazess also discloses the following limitations:

- *said processor is arranged to apply the norm to the measurements obtained by said modality to provide an indication of a normal or abnormal condition; (see at least Mazess column 15 line 46 – 66);*
- *said processor is arranged in connection with said modality; (see at least Mazess column 6 line 28 – 38 and column 7 line 3 - 12).*

20. Claims 15 – 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazess et al. (US 6,160,866 A) and in further view Barry et al. (US 6,081,786 A) and in further view of Wong et al. (US 6,260,021 B1).

CLAIMS 15 - 17

The combination of Mazess/Barry discloses the limitations shown above. Mazess/Barry does not disclose the following limitation, however, Wong does:

- *modality is arranged to express the measurements of the patient and the derived values relating to physical conditions of the patient in XML syntax; (see at least Wong column 12 line 6 – 13 and column 13 line 34 – 37);*
- *repository of medical information about the patient is arranged to remotely communicate with said processor using HL7 messaging using XML syntax; (see at least Wong column 12 line 6 – 13 and column 13 line 34 – 37);*
- *library of norms is arranged to express the norms in XML syntax; (see at least Wong column 12 line 6 – 13 and column 13 line 34 – 37).*

It would be obvious to one of ordinary skill in the art at the time of the invention to modify the measurement system of Mazess/Barry with the image formats of Wong because using these standards enables uniform access and ready distribution of medical images and associated records in electronic form (see Wong column 1 line 7 – 10).

21. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mazess et al. (US 6,160,866 A) and in further view Barry et al. (US 6,081,786 A) and in further view of **Official Notice**.

CLAIM 18

The combination of Mazess/Barry discloses the limitations shown above. Mazess/Barry does not disclose the following limitation:

- *library of guidelines is arranged to describe the guidelines using a methods ontology based on semantic web technology.*

However, Examiner takes **Official Notice** that it is old and well known in the art that data accessed over the Internet uses methods ontology (i.e. independent of the application program) based on semantic web technology (i.e. Resource Description Framework (RDF)). Therefore it would be obvious to one of ordinary skill in the art at the time of the invention to modify the measurement system of Mazess/Barry with the **Official Notice** taken because using standard data transfer methods and technology allows such data to be transferred easily over the Internet by a number of different applications.

CONCLUSION

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **John A. Pauls** whose telephone number is **(571) 270-5557**. The Examiner can normally be reached on Monday-Friday, 9:30am-5:00pm. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **JERRY O'CONNOR** can be reached at **571.272.6787**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866.217.9197** (toll-free).

Any response to this action should be mailed to:

Commissioner of Patents and Trademarks

Washington, D.C. 20231

or faxed to (571) 273-8300.

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Date: 4 March 2009

/JOHN A. PAULS/

Examiner, Art Unit 4114

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686